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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/578,130

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Alexander Von Weymarn-Scharli

A013-5786 (PCT)

4982

Adams & Wilks
Suite 1231
17 Battery Place
New York, NY 10004

7590

01/11/2010

EXAMINER

HANRAHAN, BENEDICT L

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/578,130

Applicant(s)VON WEYMARN-SCHARLI,
ALEXANDER**Examiner**

BENEDICT L.C. HANRAHAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-29 is/are pending in the application.
4a) Of the above claim(s) 22-29 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 10-21 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 10-21 in the reply filed on 10/22/2009 is acknowledged. The traversal is on the ground(s) that the claims have been amended and are no longer restrictable. This is not found persuasive because Group I and Group II do not relate to a single general inventive concept. Group I requires a control device and specifies the material of the device must be flexible and torsionally resistant.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 22-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/22/2009.

Claims Status

3. Claims 1-9 are canceled, claims 10-21 are examined on the merits and claims 22-29 are withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US 6,203,525; hereinafter Whayne) in view of Bai (US 4,619,643).

6. Regarding claims 10 and 11, Whayne discloses a device 10 (Fig 1) for at least partial introduction into a body passage, the device comprising: a long, outer envelope body 36 (Figs. 1, 8A and 8B); a long inner body 12 and 28 (Figs. 1, 8A and 8B) that is at least partially peripherally surrounded by the envelope body 36 (Figs. 1, 8A and 8B); and a control device 20 (Figs. 1, 8A and 8B) that enables and impedes relative movement between the envelope body and the inner body to respectively impart flexibility and rigidity to the entire device in a controllable manner (Col 10, lines 11-29); wherein the control device 20 (Figs. 1, 8A and 8B) is itself formed by the arrangement and embodiment of the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B) and comprises no additional mechanical means in an annular intermediate region (Fig 8B, space between outer body 36 and the inner body 28) between the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B); the material of the envelope body and the inner body is flexible yet torsionally resistant (Col 1, lines 46-49 and 55-60) and the envelope body and the inner body can be rotated relative to one another by the control device in such a way that the inner body makes contact at least partially with the envelope body (The shape of the inner and outer bodies impedes the coaxial rotational of the bodies relative to each other; Col 10, lines 11-29).

Whayne discloses that the geometry of the inner and outer body may be changed in order to prevent rotation but does not specifically disclose that the envelope body and the inner body each have a polygonal cross section. However, Bai discloses a double lumen catheter that is easy to insert and withdraw and prevents blood clotting and buckling (Col 1, lines 26-32 and 55-62

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and Col 3, lines 8-19) where the inner and outer bodies have a polygonal cross section and the corners are lined up as shown in Figures 3c - 3e. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Whayne's reference, to include a polygonal cross section, as suggested and taught by Bai, for the purpose of making the outer body as small possible while still imparting structural rigidity so as to make insertion easy but prevent the chance of buckling.

Whayne and Bai do not specifically disclose a hexagonal cross section. The combination of Whayne and Bai disclose a cross section with three sides but do not disclose six sides. Applicant has not disclosed the criticality having six sides versus three sides. It would be obvious to one skilled in the art at the time of the invention that six sides may have been used instead of three to impart structural rigidity, ease insertion of the device, and allow the shape of the outer configuration to adapt to different geometries within a body region (Whayne, Col 1, lines 46-49). Please also see MPEP 2144.04 section IV part A: In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

7. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US 6,203,525; hereinafter Whayne) in view of Bai (US 4,619,643) and in further view of Avellanet et al. (US 5,542,938; hereinafter Avellant).

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8. Regarding claims 12 and 14, Wayne discloses a control device 20 (Figs. 1, 8A and 8B) but does not specifically disclose the introduction of a pressure medium to the annular intermediate region between the envelope body and the inner body. However, Avellant discloses a magnetic guidewire coupling for catheter exchange that has a balloon expanded by filling it with a liquid. The balloon is used to change the contour and geometry in the cardiovascular system (Col 1, lines 21-25 and 54-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include liquid to be filled in a balloon, as suggested and taught by Avellant, for the purpose of being able to contour the cardiovascular system in order to create lesions with the desired geometry and characteristics.

9. Regarding claims 13 and 15, Wayne discloses an envelope body 36 (Figs. 1, 8A and 8B) and an inner body 12 and 28 (Figs. 1, 8A and 8B) and the inner body having a magnetic coating 22 (Figs. 1, 8A and 8B) but does not specifically disclose that the envelope body has a magnetic coating. However, Avellant discloses a catheter where the inner and outer body both have a magnetic coating in order to control their relative positioning to one another (Col 3, lines 44-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Wayne's reference, to include a magnetic coating on the outer envelope body, as suggested and taught by Avellant, for the purpose of being able to have better control of the catheter when it is positioned in the body, which will help increase the quality of lesions (Avellant, Col 1, lines 46-49).

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10. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US 6,203,525; hereinafter Whayne) in view of Avellanet et al. (US 5,542,938; hereinafter Avellant).

11. Regarding claim 16-17 and 20-21, Whayne discloses a device 10 (Fig 1) for at least partial introduction into a body passage, the device comprising: a long, outer envelope body 36 (Figs. 1, 8A and 8B); a long inner body 12 and 28 (Figs. 1, 8A and 8B) that is at least partially peripherally surrounded by the envelope body 36 (Figs. 1, 8A and 8B); and a control device 20 (Figs. 1, 8A and 8B) that enables and impedes relative movement between the envelope body and the inner body to respectively impart flexibility and rigidity to the entire device in a controllable manner (Col 10, lines 11-29); wherein the control device 20 (Figs. 1, 8A and 8B) is itself formed by the arrangement and embodiment of the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B) and comprises no additional mechanical means in an annular intermediate region (Fig 8B, space between outer body 36 and the inner body 28) between the envelope body 36 (Figs. 1, 8A and 8B) and the inner body 12 and 28 (Figs. 1, 8A and 8B). Whayne discloses the inner body having a magnetic coating 22 (Figs. 1, 8A and 8B) and the application of an electrical voltage (Col 5, lines 53-59).

Whayne does not disclose that the control device and the envelope body and the inner body are embodied in such a way that magnetic fields of different polarity are capable of being generated along the length of the envelope body and along the length of the inner body for the selective production of a mutual attraction of the two bodies. However, Avellant discloses a catheter where the inner and outer body both have a magnetic coating in order to control their relative positioning to one another (Col 3, lines 44-54). Therefore, it would have been obvious

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to one of ordinary skill in the art at the time of invention was made to modify the Whayne's reference, to include a magnetic coating on the outer envelope body, as suggested and taught by Avellant, for the purpose of being able to have better control of the catheter when it is positioned in the body, which will help increase the quality of lesions (Avellant, Col 1, lines 46-49).

12. Regarding claim 18, Whayne discloses a control device 20 (Figs. 1, 8A and 8B) but does not specifically disclose the introduction of a pressure medium to the annular intermediate region between the envelope body and the inner body. However, Avellant discloses a magnetic guidewire coupling for catheter exchange that has a balloon expanded by filling it with a liquid. The balloon is used to change the contour and geometry in the cardiovascular system (Col 1, lines 21-25 and 54-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Whayne's reference, to include liquid to be filled in a balloon, as suggested and taught by Avellant, for the purpose of being able to contour the cardiovascular system in order to create lesions with the desired geometry and characteristics.

13. Regarding claim 19, Whayne discloses an envelope body 36 (Figs. 1, 8A and 8B) and an inner body 12 and 28 (Figs. 1, 8A and 8B) and the inner body having a magnetic coating 22 (Figs. 1, 8A and 8B) but does not specifically disclose that the envelope body has a magnetic coating. However, Avellant discloses a catheter where the inner and outer body both have a magnetic coating in order to control their relative positioning to one another (Col 3, lines 44-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Whayne's reference, to include a magnetic coating on the outer envelope body, as suggested and taught by Avellant, for the purpose of being able to have better

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control of the catheter when it is positioned in the body, which will help increase the quality of lesions (Avellant, Col 1, lines 46-49).

Response to Arguments

14. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENEDICT L.C. HANRAHAN whose telephone number is (571)270-7854. The examiner can normally be reached on Monday-Friday, 8AM-5PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. L. H./

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761